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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,534	11/24/2003	Jack D. Burton	330651	3647

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PATENT DOCKETING
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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,534	BURTON ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2, 3, 5 and 20, drawn to a targeting moiety comprising a conjugate of an antibody specific to CEA linked to the ligand-binding region of IL-2α, classified in class 530, subclass 388.85.

II. Claims 2, 3, 5, 7, 12, 20 and 21, drawn to a targeting moiety comprising a conjugate of an antibody specific to CEA linked to the ligand-binding region of IL-4α, classified in class 530, subclass 388.85.

III. Claims 2, 3, 5, 8, 10, 20, 22 and 23, drawn to a targeting moiety comprising a conjugate of an antibody specific to CEA linked to the ligand-binding region of IL-15Rα, classified in class 530, subclass 388.85.

IV. Claims 2, 3, 6 and 20, drawn to a targeting moiety comprising a conjugate of an antibody specific to HLA-DR linked to the ligand-binding region of IL-2α, classified in class 530, subclass 388.85.

V. Claims 2, 3, 6, 7, 11, 20 and 21, drawn to a targeting moiety comprising a conjugate of an antibody specific to HLA-DR linked to the ligand-binding region of IL-4α, classified in class 530, subclass 388.85.

VI. Claims 2, 3, 6, 8, 9, 20, 22 and 23, drawn to a targeting moiety comprising a conjugate of an antibody specific to HLA-DR linked to the ligand-binding region of IL-15Rα, classified in class 530, subclass 388.85.

VII. Claims 2, 3, 14 and 20, drawn to a targeting moiety comprising a

conjugate wherein the antibody is specific for a cell marker specific to a malignant B-cell linked to the ligand-binding region of IL-2α, classified in class 530, subclass 388.73.

VIII. Claims 2, 3, 7, 14, 20 and 21, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a malignant B-cell linked to the ligand-binding region of IL-4α, classified in class 530, subclass 388.73.

IX. Claims 2, 3, 8, 14, 20, 22, 23 and 25, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a malignant B-cell linked to the ligand-binding region of IL-15Rα, classified in class 530, subclass 388.73.

X. Claims 2, 3, 15 and 20, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a activated B-cell linked to the ligand-binding region of IL-2α, classified in class 530, subclass 388.73.

XI. Claims 2, 3, 7, 15, 20 and 21, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a activated B-cell linked to the ligand-binding region of IL-4α, classified in class 530, subclass 388.73.

XII. Claims 2, 3, 8, 15, 20, 22, 23 and 26, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a activated B-cell linked to the ligand-binding region of IL-15Rα,

classified in class 530, subclass 388.73.

XIII. Claims 2, 3, 16 and 20, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a normal B-cell linked to the ligand-binding region of IL-2α, classified in class 530, subclass 388.73.

XIV. Claims 2, 3, 7, 16, 20 and 21, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a normal B-cell linked to the ligand-binding region of IL-4α, classified in class 530, subclass 388.73.

XV. Claims 2, 3, 8, 16, 20, 22, 23 and 27, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a normal B-cell linked to the ligand-binding region of IL-15Rα, classified in class 530, subclass 388.73.

XVI. Claims 2, 3, 18, 20 and 38, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a malignant T-cell linked to the ligand-binding region of IL-2α, classified in class 530, subclass 388.75.

XVII. Claims 2, 3, 7, 18, 20, 21 and 38, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a malignant T-cell linked to the ligand-binding region of IL-4α, classified in class 530, subclass 388.75.

XVIII. Claims 2, 3, 8, 18, 20, 22, 23, 29 and 38, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to a malignant T-cell linked to the ligand-binding region of IL-15Rα, classified in class 530, subclass 388.75.

XIX. Claims 2, 3, 19, 20 and 38, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to an activated T-cell linked to the ligand-binding region of IL-2α, classified in class 530, subclass 388.75.

XX. Claims 2, 3, 7, 19, 20, 21 and 38, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to an activated T-cell linked to the ligand-binding region of IL-4α, classified in class 530, subclass 388.75.

XXI. Claims 2, 3, 8, 19, 20, 22, 23, 29 and 38, drawn to a targeting moiety comprising a conjugate wherein the antibody is specific for a cell marker specific to an activated T-cell linked to the ligand-binding region of IL-15Rα, classified in class 530, subclass 388.75.

XXII. Claim 4, drawn to a targeting moiety comprising a bispecific antibody with a first specificity for a cell marker specific to a target cell and a second specificity for the ligand-binding region, classified in class 530, subclass 387.3.

XXIII. Claim 37, drawn to a targeting moiety comprising a conjugate of an antibody specific to HLA-DR linked to the ligand-binding region of IL-13Rα, classified in class 530, subclass 388.85.

XXIV. Claim 32, drawn to a method of treatment wherein a targeting moiety comprising an antibody specific to a cell marker specific to a malignant B-cell, linked to the ligand-binding region of IL-15Rα is administered to a subject, and then a conjugate of IL-15 linked to a drug, radionucleotide or toxin is administered to the subject, classified in class 424, subclass 134.1.

XXV. Claim 33, drawn to a method of treatment wherein a targeting moiety comprising an antibody specific to a cell marker specific to an activated B-cell, linked to the ligand-binding region of IL-15Rα is administered to a subject, and then a conjugate of IL-15 linked to a drug, radionucleotide or toxin is administered to the subject, classified in class 424, subclass 134.1.

XXVI. Claim 34, drawn to a method of treatment wherein a targeting moiety comprising an antibody specific to a cell marker specific to a normal B-cell, linked to the ligand-binding region of IL-15Rα is administered to a subject, and then a conjugate of IL-15 linked to a drug, radionucleotide or toxin is administered to the subject, classified in class 424, subclass 134.1.

XXVII. Claims 35 and 36, drawn to a method of treatment wherein a targeting moiety comprising an antibody specific to a malignant T-cell, linked to the

ligand-binding region of IL-15Rα is administered to a subject, and then a conjugate of IL-15 linked to a drug, radionucleotide or toxin is administered to the subject, classified in class 424, subclass 138.1.

Claim 1 links inventions of Groups I-XXI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 1. Claims 13 and 24 link inventions of Groups VII-XV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 13 and 24. Claims 17 and 28 link inventions of Groups XVI-XXI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 17 and 28. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C.

121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 30 links inventions of Groups XXIV-XXVII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 30. Claim 31 links inventions of Groups XXIV-XXVI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 31. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions are independent or distinct, each from the other because:

Inventions of Groups (I-III), (IV-VI and XXIII), (VII-IX), (X-XII), (XIII-XV), (XVI-XVIII), (XIX-XXI), and XXII represent separate and distinct products, which are made by materially different methods, and are used in materially different methods. The inventions of Groups (I-III), (IV-VI), (VII-IX), (X-XII), (XIII-XV), (XVI-XVIII), (XIX-XXI), XXII and XXIII are all distinct from each other as the antibodies recognize different antigens and therefore differ structurally and functionally. For example, the antibody-conjugate of Group (I-III) only binds the antigen CEA, which is not required by any of the other groups. Similarly, the other antibody-conjugates in the above Groups bind specific antigens, which are not required by the other groups. Finally, the bispecific antibody of Group XXII requires specificity for two antigens, which is not required by any other group. These antibody conjugates are patentably distinct because the specific antigens they target require functionally and structurally distinct antibodies. Therefore art on one antibody would not necessarily be art on the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups (I-III), (IV-VI and XXIII), (VII-IX), (X-XII), (XIII-XV), (XVI-XVIII), (XIX-XXI), and XXII are patentably distinct.

Inventions of Groups (I, IV, VII, X, XIII, XVI and XIX), (II, V, VIII, XI, XIV, XVII and XX), (III, VI, IX, XII, XV, XVIII, and XXI) and XXIII represent separate and distinct products, which are made by materially different methods, and are used in materially different methods. The inventions of Groups (I, IV, VII, X, XIII, XVI and XIX), (II, V, VIII,

XI, XIV, XVII and XX), (III, VI, IX, XII, XV, XVIII, and XXI) and XXIII are all distinct from each other as the antibodies are linked to different ligand binding regions and therefore differ structurally and functionally. For example, the antibody-conjugates of Groups I, IV, VII, X, XIII, XVI and XIX are linked to the ligand binding region of IL-2α, the antibody-conjugates of Groups II, V, VIII, XI, XIV, XVII and XX are linked to the ligand binding region of IL-4α, the antibody-conjugates of Groups III, VI, IX, XII, XV, XVIII, and XXI are linked to the ligand binding region of IL-15Rα and the antibody-conjugate of Group XXIII is linked to IL-13Rα. The ligand binding regions of these four receptors are distinct in that they have different structures, specificities, are expressed at different levels on different cell types, and have different functions and effects. Therefore art on one ligand binding region would not necessarily be art on the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups (I, IV, VII, X, XIII, XVI and XIX), (II, V, VIII, XI, XIV, XVII and XX), (III, VI, IX, XII, XV, XVIII, and XXI) and XXIII are patentably distinct.

The methods of Inventions of Groups XXIV, XXV, XXVI, and XXVII differ in the parameters and reagents used. The invention of Group XXIV recites a method of treatment wherein a targeting moiety comprising an antibody specific to a cell marker specific to a malignant B-cell, linked to the ligand-binding region of IL-15Rα is administered to a subject, and then a conjugate of IL-15 linked to a drug, radionucleotide or toxin is administered to the subject. The invention of Group XXV recites a method of treatment wherein a targeting moiety comprising an antibody

specific to a cell marker specific to an activated B-cell, linked to the ligand-binding region of IL-15Rα is administered to a subject, and then a conjugate of IL-15 linked to a drug, radionucleotide or toxin is administered to the subject. The invention of Group XXVI recites a method of treatment wherein a targeting moiety comprising an antibody specific to a cell marker specific to a normal B-cell, linked to the ligand-binding region of IL-15Rα is administered to a subject, and then a conjugate of IL-15 linked to a drug, radionucleotide or toxin is administered to the subject. The invention of Group XXVII recites a method of treatment wherein a targeting moiety comprising an antibody specific to a malignant T-cell, linked to the ligand-binding region of IL-15Rα is administered to a subject, and then a conjugate of IL-15 linked to a drug, radionucleotide or toxin is administered to the subject. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups XXIV, XXV, XXVI, and XXVII are separate and distinct in having different parameters, reagents used and endpoints and are patentably distinct.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

David Blanchard
AU 1643